EXHIBIT B-3

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

PEOPLE OF THE STATE OF NEW YORK, *Plaintiff,* v. PHARMACIA CORP., *Defendant.*	Index No. 904-03 Hon. Louis C. Benza
PEOPLE OF THE STATE OF NEW YORK, *Plaintiff,* v. GLAXOSMITHKLINE, PLC, et al., *Defendants.*	Index No. 905-03 Hon. Louis C. Benza
PEOPLE OF THE STATE OF NEW YORK, *Plaintiff,* v. AVENTIS PHARMACEUTICALS INC., *Defendant.*	Index No. 1150-03 Hon. Louis C. Benza

DEFENDANTS' CONSOLIDATED REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Dated: February 20, 2004

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INTRODUCTION

The State's Opposition to Defendants' Motion to Dismiss ("Opp.") does not dispute that the State has long been aware that AWPs exceed the costs actually paid by health care providers. Instead, the State contends that Congress has not "authorized" or "condoned" Defendant pharmaceutical manufacturers' alleged practices of reporting "inflated" AWPs. But Congressional "authorization" or "condoning" were not the basis of the motion to dismiss. Defendants rely on the government reports and legislative history not to show "authorization" but to show that the State was on notice of the pricing practices they now challenge. Thus, the State's extended effort to interpret legislative history and impose its "plain" reading of the term AWP is simply irrelevant.

What is relevant is whether the State can proceed with its five state-law causes of action -- each of which is a variation on a theme alleging fraud, deception, and misrepresentation -- in the face of a long public record establishing that responsible federal and State officials were well aware that published AWPs were typically not an accurate reflection of drug acquisition costs. Because the State was concededly aware of that fact, its fraud and deception-based claims fail.

It is also clear that if the State has any claims at all, they are limited to the relatively few drugs identified in the Complaints that were reimbursed under the Medicare program. The only specific allegations in the three Complaints filed against Defendants appear to have been lifted from one of the series of federal government reports on pricing practices in the Medicare program. Medicare historically has paid for very few drugs, primarily those that are administered by a physician (usually, by injection) or used in conjunction with durable medical equipment. Medicaid and the state-run EPIC program, by contrast, cover a wide variety of drugs, the majority of which are dispensed through pharmacies. The State's Complaints make

specific allegations as to the "spread" between prices and AWPs for a few of Defendants' products covered by Medicare Part B. The Complaints then leapfrog with no apparent justification and no specificity from this small set of drugs into sweeping allegations concerning pricing for pharmacy-dispensed drugs covered by the Medicaid and EPIC programs. Similar efforts have been rebuffed in other AWP cases by a federal district court in Massachusetts and a state court in Connecticut, and the same result is required here.

Even if the Court limits the State's claims to those drugs covered by Medicare Part B, the State cannot shoehorn the actions alleged into any cognizable legal theory. For each of the five counts, the State has failed to allege, and ultimately would not be able to prove, an essential element of the cause of action. Not only can the State not establish that Defendants' conduct was misleading, deceptive, or fraudulent, it cannot avoid the fact that any injury flowed directly from the decisions of federal and State officials to base reimbursement on AWP despite their knowledge that AWPs were, as the State now claims, "inflated." *See* Opp. at 28.

I. THE STATE COULD NOT HAVE BEEN DECEIVED BECAUSE IT HAS BEEN ON NOTICE FOR DECADES THAT REPORTED AWPs ARE NOT BASED ON ACTUAL ACQUISITION COSTS.

Given the extensive AWP history set forth in Defendants' opening brief, the State does not seriously dispute that it has known for many years that published AWPs are not an average of actual prices paid by purchasers. The Department of Health and Human Services ("HHS") has been reporting this fact to state agencies since 1984. Indeed, the HHS Inspector General published a study in 1992 in which it specifically found that physicians' drug invoice costs were frequently substantially lower than published AWPs for chemotherapy drugs administered in New York -- the same type of drugs that are among the few drugs named in the State's Complaints. *See* Defendants' Motion to Dismiss ("Def.'s Mot.") at 12. Remarkably, the position of the State appears to be that its knowledge of these disparities is beside the point,

because the federal government in reporting these facts did not actually "foreclose" the State from using AWP as a reimbursement standard. *See* Opp at 28.

The State cannot obscure the fact that, when it elected to base reimbursement as a percentage of AWP in its Medicaid and EPIC programs, it was on notice that published AWPs were not always derived from actual acquisition costs. The State's knowledge that AWP does not equal actual acquisition cost is most evident in its physician reimbursement rate under Medicaid. Rather than reimburse physician-administered drugs at a rate based on AWP, the State has chosen to reimburse physicians based on actual cost. This fact, although glossed over in the State's Opposition, definitively establishes that the State has known since at least 1991 that AWP does not equal actual acquisition cost and that it chose to reimburse physicians differently than pharmacists under Medicaid. The State concedes that it does not seek to recover for reimbursements made for physician-administered drugs under Medicaid because those reimbursements are not based on AWP. Opp. at 6. Similarly, the State cannot recover under EPIC for physician-administered drugs because that program does not pay for such drugs.

The State acknowledges that the federal Center for Medicare & Medicaid Services "suggested" to state agencies that AWPs were "inflated." Opp. at 28. The State cannot and does not deny that it still chose to base reimbursement on AWP despite the admonitions it received from CMS. The State tries to sidestep this critical point, instead devoting a large portion of its brief to attacking an argument that Defendants have not made. *See* Opp. at 13-27. The State's arguments about the definition of AWP under the 1997 Medicare Act, and about Congress's or the New York Legislature's "intent" in enacting the AWP standard for reimbursement, miss the point. Defendants' motion to dismiss does not turn on the statutory definition of AWP. Rather, Defendants argue that because the State was on notice that published

AWPs did not always reflect the prices paid in the marketplace, their conduct could not possibly have been "deceptive," and the State cannot claim to have been "deceived." The numerous public reports detailed in Defendants' opening brief were not cited, as the State assumes, to define AWP, but rather to demonstrate that the State has known for years that published AWPs were "inflated."

Thus, the State's repeated reliance on Judge Stearns's decision in *In re Lupron Mktg. & Sales Practices Litig.*, 2003 U.S. Dist. LEXIS 21496 (D. Mass. Nov. 25, 2003), is misplaced. In that case, defendants argued -- and Judge Stearns rejected -- the idea that Congress had "condoned" the alleged AWP scheme. Here, Defendants contend only that the federal and State governments knew that published AWPs were not based on actual costs and that Defendants' conduct therefore could not have been "deceptive." Judge Stearns did not address this point.

Finally, even if the meaning of AWP in the Medicare statute was relevant to Defendants' motion, the State's attempt to apply dictionary definitions to the terms "average" "wholesale" and "price" is at odds with the three Complaints it has filed against Defendants, as well as its own settled practice. The Complaints expressly recognize that a standard markup is added by the drug pricing publications to reported wholesale acquisition costs to derive the average wholesale price. Aventis and GSK Cplts. ¶¶ 15-17. Moreover, to the extent the State reimburses based on AWP, it does so only after taking a percentage reduction, which it would not do if it believed the AWP to reflect the actual cost to the provider. The fact that the State's own practices belie the "plain meaning" approach to AWP shows that it is an industry term of art, and consideration of the regulatory and legislative context is important in determining the meaning of such terms. *See Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974)

("[W]here Congress has used technical words or terms of art, 'it (is) proper to explain them by reference to the art or science to which they (are) appropriate.'"); *Commonwealth of Massachusetts v. Blackstone Valley Elec. Co.*, 67 F.3d 981, 986-88 (1st Cir. 1995) (plain meaning approach to terms of art is misplaced). As discussed in Defendants' opening memorandum, AWPs have been understood for years throughout the industry and by Medicaid and Medicare officials to be undiscounted lists prices or "sticker prices" which generally did not reflect what was being paid in the market.

The relevant question under GBL § 349 is whether the Defendants' conduct was ***deceptive***. An action cannot be deceptive if it is has no capacity to deceive. Here, there was no capacity to deceive in light of the common knowledge among state and federal regulators that the AWPs reported by the pricing services were not reflective of actual costs and in most cases were significantly higher. In sum, the State's knowledge that AWPs did not reflect actual acquisition costs refutes any argument that Defendants' conduct could have been "deceptive" or "misleading." For this reason, the State's claims under § 349 (First Cause of Action), as well as its claims under Executive Law § 63(12) for "repeated and persistent fraud" (Second Cause of Action), should be dismissed.

II. THE STATE CANNOT EXTRAPOLATE FROM THE FEW MEDICARE COVERED DRUGS IDENTIFIED IN THE COMPLAINT TO THE MANY OTHERS THAT THE STATE PAYS FOR THROUGH MEDICAID AND EPIC.

New York procedure rules require that statements in a pleading "be sufficiently particular" as to "the transactions, occurrences or series of occurrences" intended to be proved "and the material elements of each cause of action or defense." CPLR § 3013. Moreover, "[w]here a cause of action or defense is based upon misrepresentation, fraud . . . breach of trust or undue influence, the circumstances constituting the wrong *shall be stated in detail.*" CPLR § 3016(b). In light of these requirements, the Complaints must include, at the very least, specific

allegations as to which of Defendants' thousands of drugs were subject to allegedly fraudulent price reporting, and what AWPs or "other pricing information" was allegedly inflated. Yet all that the Complaints contain are recitations that AWP does not reflect a provider's actual acquisition costs, some general statistics on federal Medicare expenditures on a few drugs in one, unspecified year, and isolated allegations about the "spreads" for a few Medicare Part B covered drugs.

It is telling that the only drugs expressly named in the Complaints are among the very few that are covered by the Medicare program (prior to the recent expansion of the program, which is not scheduled to take place until 2006). Medicare is wholly unlike Medicaid and EPIC in that: (1) it reimburses for very few drugs; (2) the drugs which it covers are almost exclusively administered by a physician, who generally will also be the prescriber; and (3) the patient receiving the drug must generally pay a co-payment based on the Medicare reimbursement level. By contrast, Medicaid and EPIC cover a huge number of different drugs, most (and, in the case of EPIC, all) of which are dispensed through pharmacies that do not have prescribing authority, and the co-payments, if any, are imposed at a flat rate (or, in the case of EPIC, at a tiered rate).

The State does not dispute that each of the drugs identified in the Complaints is a drug that is typically physician-administered and covered by Medicare Part B. It contends, however, that these are only a "few examples" of the drugs it seeks to include in these cases. Opp. at 56. However, it has failed to allege any facts that would in any way tie its "examples" about Medicare Part B drugs to the other drugs paid for by the Medicaid and EPIC programs. Absent specific allegations that the complained-of pricing disparities for physician-administered Medicare Part B drugs extend also to ***specifically named*** pharmacy-dispensed drugs paid for by

Medicaid and EPIC, the Complaints must be dismissed at least with respect to drugs not identified by name.

While the State is quick to cite to portions of the opinions already rendered in some of the ongoing AWP litigation in other jurisdictions, it studiously avoids that portion of the opinion from the District of Massachusetts taking just such a drug-by-drug approach. As pointed out in Defendants' initial brief, Judge Saris, who is overseeing the AWP MDL in Boston, has ruled that generalized allegations are insufficient to satisfy the particularity requirements of Federal Rule of Civil Procedure 9(b), and ordered that the case proceed drug-by-drug. *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). In that case, as in this one, plaintiffs sought to expand the case outside of Medicare Part B based on general allegations about the alleged AWP scheme, but plaintiffs identified in their complaint only a limited number of Medicare Part B drugs. Judge Saris rejected plaintiffs' attempt to graft the Medicare Part B allegations onto the non-Medicare Part B claims, dismissing all claims that did not identify, at a minimum, (1) ***the particular drugs involved*** and (2) the ***allegedly fraudulent AWPs*** of those drugs. *Id.* More recently, the state court presiding over the four AWP complaints brought by the State of Connecticut against various pharmaceutical manufacturers also held that the State of Connecticut must amend its complaints to specifically identify the drugs it seeks to include in the case. *See* Orders (Unpublished) Granting Requests to Revise Complaints in *State of Connecticut v. Pharmacia Corp.*, CV-03-59287-5 (X07) (Conn. Super. Ct.); *State of Connecticut v. Dey, Inc.*, CV-03-83296-5 (X07) (Conn. Super. Ct.); *State of Connecticut v. GlaxoSmithKline*, CV-03-83298-5 (X07) (Conn. Super. Ct.); *State of Connecticut v. Aventis Pharmaceuticals Inc.*, CV-03-83299-5 (X07) (Conn. Super. Ct.). The State's attempt to expand these cases beyond the drugs identified in the Complaints without any drug-specific

factual allegations whatsoever should be rejected, just as it was in the AWP MDL and Connecticut cases.

The State does not argue that it has set forth its claims with particularity. Rather, the State argues that it should be excused from providing specific allegations about the drugs involved and their AWPs because that information is solely within the knowledge of the Defendants. Opp. at 55-56. Not so. The State knows which drugs are covered by the Medicaid and EPIC programs and which of those drugs are reimbursed based on AWP. In addition, pursuant to the EPIC program, the State has the authority to obtain pricing information directly from the Defendants. Indeed, the State has received from Defendants detailed quarterly statements of the Average Manufacturers' Price ("AMP") and Best Price ("BP") for drugs covered by EPIC. *See* Def.'s Mot. at 33. The State can easily compare the AMPs to reported wholesale acquisition costs, other reported prices, AWPs, and the standard markup information referred to in its Complaints. Since the State has all the information it needs to make specific allegations about its Medicaid and EPIC drugs and the prices reported by Defendants for those drugs, it should not be excused from its failure to do so.[1]

The State also argues that CPLR § 3016(b) does not apply to its claims. This argument is meritless. The State's claim that § 3016(b) applies only to causes of action for common law fraud is contrary to the plain language of the statute. Section 3016(b) requires that causes of action or defenses based upon "misrepresentation, fraud, mistake, willful default,

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[1] Relying on an affidavit from Stephen C. Abbott, the State dismisses the relevance and significance of its receipt of AMP and BP data because the data was "confidential." The New York Department of Health oversees both the EPIC and Medicaid programs. Mr. Abbott's affidavit states only that AMP data were not shared within the Department, not that it could not have been shared. Moreover, the affidavit is silent as to the BP data received. In any event, Defendants are not asking that the State -- ***which represents EPIC in this action*** -- publicize any confidential information.

breach of trust or undue influence" be pled with particularity. Thus, the language of the statute clearly provides that causes of action based on theories other than common law fraud (*e.g.*, misrepresentation, breach of trust, etc.) are subject to a heightened pleading requirement. The State's claims under GBL § 349 (deceptive acts) and Exec. Law § 63(12) (repeated and persistent fraud in conducting business) are plainly based on allegations of "misrepresentation" or "fraud." Indeed, the Complaints are replete with allegations that the Defendants engaged in "fraud" or "misrepresentations." *See, e.g.*, Cplts. ¶¶ 27 (citing Defendants' alleged "fraudulent and deceptive misrepresentations"); Pharmacia Cplt. ¶ 24 and GSK & Aventis Cplts. ¶¶ 25 (alleging that Defendants "misrepresented" the AWPs of their drugs).[2]

The State attempts to ignore the precise language of Section 3016(b) and circumvent its application by citing to *Banks v. Consumer Home Mortg., Inc.*, 2003 WL 21251584 (E.D.N.Y. Mar. 28, 2003) and *John P. Villano Inc. v. CBS, Inc.*, 176 F.R.D. 130, 131 (S.D.N.Y. 1997). Both of those cases, however, held only that Federal Rule of Civil Procedure 9(b) does not apply to deceptive practices or false advertising claims. They did not address the application of § 3016(b), which requires particularity not just for claims based on "fraud," but also for claims based on "misrepresentation," "breach of trust," and "undue influence." Similarly, the courts in *Brady v. Publishers Clearing House*, 787 A.2d 111 (Del. Ch. 2001) and *Leake v. Sunbelt Limited of Raleigh*, 93 N.C. App. 199 (1989), also relied upon by the State,

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[2] Also meritless is the State's argument that Section 3016(b) does not apply to its commercial bribery claims. While bribery is not among the causes of action listed in the statute, the State has constructed its commercial bribery claims based on the alleged fiduciary duties of physicians towards their patients. Cplts. ¶¶ 36. Having done so, it cannot avoid the heightened pleading rules of Section 3016(b), which apply to causes of action based upon "breach of trust" and "undue influence."

Opp. at 54, were construing statutes modeled after Rule 9(b), which has narrower language than § 3016(b).

In any event, numerous other federal courts have held that Rule 9(b) does apply to § 349 deceptive practices claims. *See, e.g.*, *Rey-Willis v. Citibank, N.A.*, 2003 WL 21714947, at *7 (S.D.N.Y. July 23, 2003) (dismissing § 349 claim because plaintiff failed to satisfy the requirements of Rule 9(b)); *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003) (same); *Sichel v. Unum Provident Corp.*, 230 F. Supp. 2d 325, 330-31 (S.D.N.Y. 2002) (dismissing a § 349 claim where the pleading was "not supported by specific and detailed factual allegations"); *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 100 (S.D.N.Y. 1997) (internal citation omitted) ("In pleading a claim under the Consumer Protection Act, a Plaintiff is required to set forth specific details regarding the allegedly deceptive acts or practices.").

Under any of these pleading standards, the State's efforts to extrapolate from the few Medicare Part B drugs identified in the Complaints to all drugs covered by Medicaid and EPIC must be rejected, as the State has failed adequately to plead any specific facts relating to drugs reimbursed based on AWP under those programs.[3]

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[3] In addition, even the State's allegations with respect to the handful of Medicare Part B drugs named in the Complaints are deficient. As Judge Saris held in *In re Pharmaceutical Industry*, a complaint must identify not only the drugs involved but also the allegedly fraudulent AWPs of those drugs. 263 F. Supp. 2d at 194. Not only does the State fail to identify the AWP of a single drug -- a failure that is itself fatal to the State's claims -- the State has not even made clear what prices it claims Defendants falsely reported. *See* Def.'s Mot. at 38. The State completely ignores both of these crucial pleading requirements, claiming instead that it should be excused from pleading its case with particularity. That position is wholly without merit and should be rejected.

III. THE STATE FAILS TO STATE A COGNIZABLE LEGAL THEORY THAT WOULD PERMIT THE CASE TO PROCEED.

A. The State's Failure to Allege Conduct Resulting in Injury is Fatal to Its Claim for Restitution Under GBL § 349 And Executive Law § 63(12).

The State claims that unlike a private individual, the Attorney General need not allege that Defendants' actions caused injury to state a claim under § 349. Opp. at 38-39. The State is incorrect. Section 349 specifically provides that the State can recover restitution only of "moneys or property obtained directly or indirectly by any such unlawful acts or practices." Gen. Bus. L. § 349(b). The legislative history further demonstrates that the Attorney General has only the "powers to obtain restitution for *defrauded* customers in such proceedings." Governor's Mem. approving L. 1970, chs. 43 & 44, 1970 N.Y. Legis. Ann., at 472 (emphasis added). Thus, that statute expressly requires causation of injury. Indeed, the State implicitly acknowledges that it can only recover overpayments made "*as a result of* defendants' deceptive conduct." Opp. at 37 (emphasis added).

The case law confirms that damages or restitution cannot be awarded absent proof of injury and causation. For example, in *People v. Appel*, 685 N.Y.S.2d 504, 258 A.D.2d 957 (N.Y. App. Div. 4th Dept. 1999), the appellate division reversed a trial court's award of damages after it found that the defendant had organized a deceptive scheme to induce authors to submit manuscripts to a company for editing. In that case, the Fourth Department held that the trial court abused its discretion in "ordering restitution in the full amount of the fees received" by respondents because "*[t]here is no proof regarding what percentage of those revenues is attributable to respondents' deception*." 685 N.Y.S.2d at 505, 258 A.D.2d at 958 (emphasis added). *See also State v. Management Transition Resources, Inc.*, 454 N.Y.S.2d 513, 515, 115 Misc. 2d 489, 492 (Sup. Ct 1982) (§ 63(12) and GBL § 349(b) "expressly authorize the granting of restitution to consumers *injured by* a respondent's fraud.") (emphasis added); *State v.*

Feldman, 210 F. Supp. 2d 294, 303 (S.D.N.Y. 2002) (internal citation omitted) (§ 63(12) "authorizes the New York Attorney General to recover for non-residents *injured by wrongdoing* that occurred in New York.") (emphasis added).

Each of the cases cited by the State stands for the proposition that the Attorney General can seek *injunctive* relief to prevent a deceptive practice without waiting for an allegation of injury or an actual complaint to be filed.[4] The State has not cited a single case, however, for the proposition that it can seek *restitution* without alleging actual injury caused by a materially deceptive act. Indeed, it cannot. *See Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25, 623 N.Y.S.2d 529, 532 (N.Y. 1995) (internal citation omitted) ("A prima facie case requires . . . a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof"). While the State implicitly acknowledges that causation is required -- noting on page 37 of its brief in bold type that it is entitled "to recover restitution for all overpayments

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[4] *See Goshen v. Mutual Life Ins. Co. of New* York, 98 N.Y.2d 314, 324, 746 N.Y.S.2d 858, 863 (internal citations omitted) (2002) ("New York's Consumer Protection Act . . . was enacted to provide consumers with a means of redress for injuries caused by unlawfully deceptive acts and practices . . . Unlike private plaintiffs, the Attorney General may, for example, seek injunctive relief without a showing of injury"); *State v. Lipsitz*, 663 N.Y.S.2d 468, 474-79, 174 Misc.2d 571, 580, 584 (Sup. Ct. 1997) (noting Attorney General can commence enforcement action in absence of complaint but requiring accounting for order of restitution); *State v. Management Transition Resources*, 454 N.Y.S.2d 513, 515, 15 Misc.2d 489, 491 (Sup. Ct. 1982) ("It is not necessary for the Attorney General to await consumer complaints before proceeding to enjoin this chicanery."); *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 273 (1977) (City of New York may enjoin deceptive acts or practices without showing that consumers were injured) (relying on City of New York Admin. Code § 2203d-4.0(e), renumbered § 20-703(e), which specifically provides that the City need not allege injury, not GBL § 349).

Here, the State's own allegations negate the need for an injunction of future conduct. The Complaints reflect the State's view of the information Defendants report to outside services. The State can decide whether and how to use this information. Indeed, the Federal Government has now enacted legislation requiring that the use of AWP as a reimbursement standard be phased out by 2005. *See* Def. Mot. at 29; Opp. at 23.

made as a result of defendant's deceptive conduct" -- it nevertheless fails to allege or explain how Defendants' actions caused injury or why the numerous intervening acts cited by Defendants in their opening brief do not fail to break the causal chain. *See* Def.'s Mot. at 46-47.

B. The State Cannot Recover Under General Business Law § 349 Because It Has Not Alleged Any Conduct Directed At Consumers

The State argues that Defendants may be liable under § 349 -- a statute designed to protect consumers from deceptive acts and practices -- without proof of deceptive acts aimed at consumers. The principal flaw in the State's argument is that Defendants' alleged conduct was aimed not at the consuming public but at the reporting services that were sometimes used by state regulators and federal officials to set varying reimbursement rates. To the extent there is any link between Defendants and the public at all, it is created by the government's decisions to use the reported information in a particular way. Even allowing the broadest possible interpretation of the law (as the State repeatedly urges), the consumer protection statute does not stretch far enough to encompass the State's novel theory of recovery.

1. The State Has Not Alleged that Defendants' Conduct is "Consumer-Oriented" as Required By § 349

The State has not alleged and cannot prove that the price reporting that is the basis of the State's claims is "consumer-oriented." *New York Univ. v. Continental Ins. Co.*, 87 N.Y.2d 308, 320 (1995) ("parties claiming benefit of [§ 349] must, at the threshold, charge conduct that is consumer-oriented. The conduct . . . must have a broad impact on consumers at large."); *see Cruz v. Nynex Info. Resources*, 703 N.Y.S. 2d 103, 107 (1st Dept. 2000) ("The threshold requirement of consumer-oriented conduct is met by a showing that 'the acts or practices have a broader impact on the consumer at large' in that they are 'directed to consumers' or 'potentially affect similarly situated consumers.'") (quoting *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 623 N.Y.S.2d 529 (1995)).

Although the federal courts have been loose with language when describing the scope of § 349, speaking generally of "harm to the public interest," the New York courts have made clear that § 349 is "directed at wrongs against the *consuming public*," *Oswego*, 623 N.Y.S.2d at 24 (emphasis added), and that the harm alleged must be harm to "*consumers at large*." *Cruz*, 703 N.Y.S.2d at 107 (emphasis added). Moreover, each of the cases cited by the State actually involves conduct *directed at public consumers*. *See, e.g., Karlin v. IVF America, Inc.*, 690 N.Y.S.2d 495, 500 (N.Y. 1999) ("multi-media dissemination" of misleading information about success rate of IVF treatment "*to the public*"); *Sterling v. Ackerman*, 663 N.Y.S.2d 842, 843 (1st Dept. 1997) (physician charged patients fees in excess of allowable Medicare charges); *Blue Cross and Blue Shield v. Philip Morris USA, Inc.*, 344 F.3d 211, 218 (2d Cir. 2003) (deceptive practice by tobacco company "*induced consumers* to smoke and discouraged them from quitting smoking"); *State v. Feldman*, 210 F. Supp. 2d 294, 301-02 (S.D.N.Y. 2002) (scheme to rig bids at *public* stamp auctions injures unsophisticated stamp sellers); *Riordan v. Nationwide Mut. Fire Ins. Co.*, 756 F. Supp. 732, 739 (S.D.N.Y. 1990)("plaintiffs expressly allege the existence of a claim settlement policy designed to deceive certain categories of policyholders; in other words, *the public at large*.") (emphasis added in all).[5]

The *Karlin* case, cited by the State, is instructive. In *Karlin*, the Court extended § 349 to defendant IVF program noting that when physicians "choose to reach out to the

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[5] To the extent *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995), cited by the State, can be interpreted as involving conduct directed at an agency "primarily concerned with the safety of the public" rather than the consuming public itself, it is best viewed as an example of the federal courts' seeming extension of § 349. It is the state courts, however, who are the "prime determiners of [s]tate law." *People v. Cephas*, 2003 WL 21783355, at *4 n.9 (Sup. Ct. N.Y. Co. May 23, 2003) ("Federal courts should defer to the State courts for the construction of state law").

consuming public at large in order to promote business -- like clothing retailers, automobile dealers and wedding singers who engage in such conduct -- they subject themselves to the standards of an honest marketplace secured by [§ 349]." 690 N.Y.S.2d at 591. Here, in contrast, the State cannot allege that the pharmaceutical manufacturers "reached out to the consuming public" by reporting price information to commercial price reporting services not used or relied upon by any public consumer.

The only consumer harm mentioned by the State in its Opposition is the possibility of increased co-payments. That is a possibility only for drugs covered by Medicare Part B, where beneficiaries are responsible for a 20% co-payment of the Medicare reimbursement. Medicaid has a set co-payment which is unaffected by the amount paid by the Medicaid program, and EPIC has a tiered co-payment based on reimbursement bands. Yet the State's allegations of incidental harm to Medicare beneficiaries do not transform Defendants' acts of reporting pricing information to publishing services into consumer-oriented conduct as required by § 349. It is the government's own conduct in deciding to utilize the information in a particular manner -- not Defendants' conduct -- that has brought the public into the mix and caused the alleged co-payment increase. *See* Def.'s Mot. at 45-47. The nexus between the remaining harms the State alleges -- *i.e.*, an "impact [on] the quality of care provided" to the public, improper prescribing of drugs by physicians, and alleged overpayments by State taxpayers and the consuming public -- and Defendants' alleged conduct is even more attenuated and simply cannot form the basis of a Section § 349 claim. *See e.g. Cruz*, 703 N.Y.S.2d at 107 (insufficient link between harm and consuming public at large to state § 349 claim). Indeed, the application of § 349 the State urges on this Court reads the word "consumer" out of the consumer protection statute.

2. The State Cannot Collect its Own Alleged Overpayments Under § 349

Unable to allege any conduct directed at consumers, the State attempts to cast itself as a consumer who can recover for restitution under § 349. But § 349 is a *consumer protection statute* and as such it authorizes the Attorney General to seek restitution solely for injuries to *consumers*. *See Genesco Entertainment Inc v. Koch,* 593 F. Supp. 743, 751 (S.D.N.Y. 1984) (§ 349 "wears its purpose on its face; it is entitled 'Consumer Protection from Deceptive Acts and Practices"). Not surprisingly, therefore, the State in its Opposition can point to nothing in the text of § 349(b) or in the case law that authorizes recovery for the State's own alleged losses, as opposed to losses incurred by *consumers*. The State cites no prior enforcement action in which it has sought recovery on behalf of itself; on the contrary, it acknowledges that § 349 is utilized by the Attorney General to "obtain relief for consumers" who have been the victims of deceptive acts. Opp. at 38.

Bereft of authority under § 349(b) -- the subsection of the statute that authorizes suits by the Attorney General -- the State turns to a line of cases interpreting § 349(h) for the proposition that it has standing to recover under the statute. Opp. at 38. The State's reliance on these cases is misplaced.

First, as Defendants argue in their opening brief and the State fails to refute, there is no indication that by creating a private right of action in subsection (h) for "persons" injured by a violation of the statute the Legislature intended to provide an alternate basis for suits by the Attorney General. *See Will v. Michigan Dep't of State Police,* 491 U.S. 58, 64 (1989) ("[I]n common usage, the term 'person' does not include the sovereign, [and] statutes employing the [word] are ordinarily construed to exclude it"); McKinney's Cons. Law of N.Y., Book 1, Statutes § 115 ("a statute does not apply to the State . . . unless it is specifically mentioned therein or included by necessary implication"); *see also* Def.'s Mot. at 45 n.39.

Second, even assuming the State is a "person" for purposes of the statute, any viable claim would have to be derivative of injuries to third party consumers and, accordingly, would likely be barred as too remote. *See Eastern States, Health, and Welfare Fund v. Philip Morris, Inc.*, 729 N.Y.S.2d 240 (Sup. Ct. N.Y. Co. 2000); *A.O. Fox Mem. Hosp. v. American Tobacco Co.*, 302 A.D.2d 413 (2d Dept. 2003). The question of whether an indirect claim is actionable under § 349(h) has been certified to the New York Court of Appeals and is presently under consideration. *See Empire Blue Cross and Blue Shield v. Philip Morris USA, Inc.*, 344 F.3d 211 (2d Cir. 2003) (certifying question); 2003 WL 22455503 (N.Y. Oct. 20, 2003) (accepting certification).

C. Executive Law § 63(12)

The State has asserted four Causes of Action under Executive Law § 63(12), none of which set forth any cognizable legal theory. As discussed in Part I, *supra*, the State's Second Cause of Action, whether predicated on GBL § 349 or some other allegation of repeated and persistent fraud, should be dismissed because, *inter alia*, the State's knowledge that AWPs do not reflect actual acquisition costs refutes its claim that Defendants' conduct was "deceptive" or that the State could have been misled. In addition, the State's remaining causes of action under Executive Law § 63(12) should be dismissed for the reasons set forth below.

1. The State Has Failed to State a Cause of Action Predicated on Penal Law Article 180

The State concedes that its claim under Executive Law § 63(12) for repeated and persistent commercial bribery in violation of Penal Law § 180.00 is predicated upon physicians breaching a fiduciary duty to their patients. Opp. at 45. Yet the State fails to allege that any physician chose a drug that was not medically appropriate. Defendants demonstrated in their opening memorandum that a physician's choice between two or more medically appropriate

drugs would not implicate a fiduciary duty to the patient. Def.'s Mot. at 51-52. The State ignores this point, instead focusing on other aspects of the physician-patient relationship that are not involved in the conduct at issue. Opp. at 45. The State does not dispute that New York law has imposed fiduciary duties on physicians ***only*** with respect to treatment decisions and confidentiality. *See* Def.'s Mot. at 51.[6]

The limited nature of the fiduciary relationships between doctors and patients underscores the failure of the State's Complaints. The State erroneously draws an analogy to the fiduciary relationship between a securities broker and his customer. *See* Opp. at 45 (citing *United States v. Szur*, 289 F.3d 200 (2d Cir. 2002)). Unlike securities brokers, physicians have ***no*** fiduciary duty with respect to their patients' financial matters. New York courts have made clear that a limited fiduciary duty based on specific aspects of a professional relationship does not translate into a general fiduciary duty on all other aspects of the relationship. For example, "it is well settled that a stockbroker buying and selling securities for a customer does not, in the ordinary conduct of business, owe a general fiduciary duty to the purchaser of securities" absent discretionary trading authority. *Davantzis v. PaineWebber Inc.*, 2001 WL 1423519 (Sup. Ct. N.Y. Cty. July 23, 2001); *see also Fesseha v. TD Waterhouse Inv. Servs.*, 747 N.Y.S.2d 676, 683, 193 Misc. 2d 253, 260 (Sup. Ct. N.Y. Cty. 2002) (no general fiduciary duty of stockbroker) (citing, *inter alia*, *Fekety v. Gruntal & Co.*, 191 595 N.Y.S.2d 190, A.D.2d 370 (1st Dept. 1993)). Thus, the State has failed to state a cause of action based on commercial bribery.

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[6] Indeed, the physician-patient cases cited by the State relate to subjects such as "speak[ing] the truth about [the patient's] medical condition," State Opp. at 46 (quoting *Aufrichtig v. Lowell*, 85 N.Y.2d 540, 546 (1995)).

The State has not alleged that the Defendants intended to influence any physician to act in a manner inconsistent with a patient's interests, or that any physician did so. Def.'s Mot. at 51-52. Indeed, under the State's novel theory of commercial bribery, even a company that reported an AWP satisfying the State's new definition would be committing commercial bribery of any physician who paid less than the arithmetical "average" wholesale price, because that physician would receive a greater "benefit" than if the physician purchased another drug at the arithmetical average. This absurd result demonstrates that the benefit conferred by the government's reimbursement formula cannot be "commercial bribery" by Defendants.

The cases the State cites do not support its convoluted theory. *In re Lupron Marketing & Sales Practices Litig.*, 2003 WL 22839966 (D. Mass. Nov. 25, 2003), from which the State quotes, Opp. at 46-47, did ***not*** involve any claim of commercial bribery. Moreover, unlike this case, that case involved allegations that a pharmaceutical company provided free samples to physicians and then instructed the physicians to bill Medicare for them. The only other case cited by the State, *Pharmacare v. Caremark*, 965 F. Supp. 1411, 1423 (D. Haw. 1996), Opp. at 47, involved allegations that the defendant corporation actually made payments to physicians acting as "public officials." In that sense, it was a classic bribery allegation. In this case, the State does not allege that Defendants made any payment to physicians. Similarly, the State's incomplete quote from the OIG Fraud Alert, 59 Fed. Reg. 65,372 (Dec. 1994) (Firestein Aff. Ex. 6), Opp. at 47, is taken from a portion of the Report specifically discussing instances in which pharmaceutical companies actually paid remuneration or provided airline frequent flier mileage to physicians or pharmacies. Nothing of the kind is alleged here.[7]

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[7] The Report also involved a unique federal statute which is not the basis for any claim here.

Finally, the State fails to respond to Defendants' showing that the commercial bribery claim -- which applies only to physician-dispensed drugs -- cannot possibly apply to EPIC (which involves only pharmacies) or Medicaid (which reimburses physicians based on actual acquisition cost). Def.'s Mot. at 50; *see also* Cplts. ¶¶ 36 (allegations directed only to physicians, not pharmacists); Def.'s Mot. at 49 n.44; N.Y. Soc. Serv. Law § 367-a(9)(a).[8]

2. The State Has Failed to State a Cause of Action Predicated on The Medicaid Anti-kickback Regulation.

In its Fourth Cause of Action, the State asserts that Defendants provided unlawful kickbacks to New York pharmacists. *See* Cplts. ¶¶ 30; 46-48. According to the State, the Defendants did so by fraudulently marketing the "spread" on their drugs to pharmacists in order to induce them to "recommend" Defendants' prescription drugs to Medicaid beneficiaries and the beneficiaries' physicians. *See id.*; *see also* Opp. at 48.[9]

Defendants' opening brief demonstrated that this claim is unsupportable because pharmacists do not choose what brand-name medications are provided to patients; rather, they fill prescriptions that are written by physicians. The State's response does not contest this fact, but nonetheless asserts that it "is not a basis for dismissal." Opp. at 49. To support this assertion, the State relies on two OIG publications that have nothing to do with the claims in these cases.

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[8] Thus, to the extent the Court permits the State to go forward on this cause of action, which it should not, at a minimum the Court should expressly limit the State to Medicare Part B drugs sold to physicians who administered this narrow class of drugs to Medicare patients.

[9] As noted in Defendants' initial memorandum, the State could not make its Medicaid kickback allegations with respect to physicians, because physician reimbursement under New York Medicaid is based on actual cost, without regard to AWP. *See* Def.'s Mot. at 54 n.51; N.Y. Soc. Serv. Law § 367-a(9)(a).

The first publication is a 1994 OIG Special Fraud Alert concerning "a product conversion program" pursuant to which a "drug company offered a cash award to pharmacies" for each instance in which they "help[ed] persuade physicians, who were unaware of the pharmacies' financial interest, to change prescriptions." Opp. at 49. Similarly, the State cites a 2003 OIG publication which "identifies payments to cover the costs of 'converting' from a competitor's product as prohibited remuneration." Opp. at 50. The State does not plead a single fact that would establish that any of the Defendants gave cash awards to pharmacists to switch drugs or had any "product conversion program."

Moreover, the cases cited by the State regarding the federal anti-kickback act are wholly inapposite and serve only to highlight the deficiencies in the State's claim. In *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989), a medical services company referred laboratory work to a diagnostic company and "kicked back" fifty-percent of the Medicare reimbursement payments to the medical services company. *See id.* at 106-07. In *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), physicians referred patients to defendant for diagnostic services, defendant then billed Medicare for the services and "kicked back" part of the Medicare payment to the physicians. *See id.* at 69-70. In *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir. 1989), an ambulance services company paid a city employee for the employee's assistance in securing an emergency services contract. *See id.* at 23-28. And in *United States v. Mittal*, 1999 WL 461293 (S.D.N.Y. July 7, 1999), a doctor received kickbacks, including cash, in exchange for referring patients to various facilities that provided medical services reimbursed by Medicare. *See id.* at *1-2. The State has pleaded no such facts in these cases. Accordingly, the State's Fourth Cause of Action should be dismissed.

3. The State Has Failed to State a Cause of Action Predicated on Soc. Serv. Law § 145-b.

In its Fifth Cause of Action, the State claims that Defendants violated Executive Law § 63(12) by repeatedly "obtaining public funds by false statements" in violation of Social Services Law § 145-b. The State alleges that Defendants knowingly made "false statements and representations or engaged in a fraudulent scheme on behalf of New York pharmacists" that resulted in the New York Medicaid and EPIC Programs overpaying for Defendants' drugs. Cplts. ¶¶ 50. [10]

As noted in Defendants' initial brief, Defendants did not attempt to "obtain payment from public funds," and therefore the State has no claim against Defendants based on § 145-b. The State asserts that it "is evident from th[e] statutory language" that § 145-b "affords the State broad authority to recover funds from individuals or entities whose fraudulent activity causes increased costs to State-funded programs." Opp. at 51. The State cites no authority for this assertion, for good reason: it is directly contradicted by the plain language of the statute. If the legislature wished to make it unlawful to "cause increased costs to State-funded programs," it easily could have done so. Instead, it enacted a statute directed at those who wrongfully "obtain" public funds. There is no allegation in the Complaints that Defendants submitted a single claim for reimbursement to the State. It is irrefutable that it was New York pharmacists, not Defendants, who sought and received payment from Medicaid and EPIC. The State, however, seeks to deflect attention from this point by asserting that "the statute's reference to 'false

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[10] As discussed more fully in Defendants' initial brief, this claim is only asserted on behalf of the State for moneys paid under the New York Medicaid and EPIC programs for drugs dispensed by pharmacists. Def.'s Mot. at 58; *see also* Opp. at 51 (Stating that Section 145-b allows the state to seek recovery of "increased costs to *state-funded programs...*") (emphasis added).

statement ... or other fraudulent scheme or device'" somehow pulls Defendants within the scope of § 145-b. *See* Opp. at 51. This assertion fails, because the language that the State quotes simply cannot be read to broaden the statute's reach beyond those who have "attempt[ed] to obtain payment from public funds."[11]

Moreover, the State acknowledges that it cannot state a claim unless Defendants' conduct directly caused "increased costs to state-funded programs." Opp. at 51. The State asserts that, "[b]ut for Defendants' submission of false price data, there would be no overpayments for drugs under EPIC or Medicaid." Opp. at 52. However, the assertion that the State was deceived into thinking that published AWPs represented actual provider acquisition costs cannot withstand even light scrutiny. This is illustrated by the simple fact, as discussed above, that the State itself does not pay AWP. In the physician context, the State reimburses based on actual acquisition cost. In the pharmacy context, the State pays a rate that is discounted from AWP. If the State's assertion that it understood AWP to be equivalent to acquisition cost were credited, it would mean that the State intends to pay pharmacies less than what it costs them to acquire the drugs. This fact alone refutes the State's assertion that it understood AWP to be equivalent to provider acquisition cost.

The State does not squarely address this issue. Rather, it relies entirely on the unpublished decision in *Kuriansky v. Kermani* (Sup. Ct. N.Y. Co. 1998). *See* Opp. at 52. However, *Kuriansky* is readily distinguishable. In that case, the State sued a psychiatrist who had already been convicted of selling "prescriptions for money, without rendering significant

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[11] *See e.g.*, *State v. Easton*, 647 N.Y.S.2d 904, 169 Misc. 2d 282 (Sup. Ct. Albany Cty. 1995) and *People v. Brooklyn Psychosocial Rehabilitation Inst.*, 585 N.Y.S.2d 776, 185 A.D.2d 230 (2d Dept. 1992) (discussing claims under N.Y. Soc. Serv. Law. § 145-b where defendants were charged with attempting to falsely *obtain* state funds).

medical services." In turn, "the prescriptions were dispensed [by pharmacies] 'without regard to need or pretense of diagnosis.'" *Id.* at 2. The State alleges no such conduct in this case. Moreover, the defendant's criminal conviction collaterally estopped him from even contesting the State's claim that he engaged in a fraudulent scheme in the first instance. Thus, *Kuriansky* is completely inapposite here. Further, to the extent that the *Kuriansky* court interpreted § 145-b to reach a defendant that does not itself obtain or attempt to obtain public funds, that interpretation is incorrect. By its plain terms, the statute is directed at "any person, firm or corporation" that acts fraudulently to "obtain payment from public funds." On the face of the statute, such a defendant may act "on behalf of ... others," but must itself obtain public funds. The statute simply cannot be read as if the legislature had said something else.

In sum, since the State does not allege that Defendants sought or obtained payment from public funds, the State's Fifth Cause of Action must be dismissed.

CONCLUSION

For the reasons set forth above and in Defendants' initial memorandum, Defendants' Motion to Dismiss should be granted.

Respectfully submitted,

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